May 10, 2019

Sent via fax to: (301) 827-9267

To: Food and Drug Administration
Division of Freedom of Information
Office of the Executive Secretariat, OC
5630 Fishers Lane, Room 1035
Rockville, MD 20857

From: Patrick Radden Keefe
c/o Daniel Novack
Penguin Random House LLC
1745 Broadway, NY, NY 10019

Dear Records Officer,

I request records under the provisions of the Freedom of Information Act. 5 U.S.C.§ 552.

I. Request

All records relating to the FDA's approval of Purdue Pharma's opioid painkiller OxyContin, in both its original and reformulated versions.

I am particularly interested in reviewing records relating to representations made by Purdue about the safety of OxyContin and the FDA's awareness - or lack thereof - of the risk of abuse and addiction.

While my request encompasses **all** records relating to the FDA's approval, I am particularly interested in the following materials - and would be happy to narrow my request if the agency is willing to proactively assist me in identifying these records of interest:

1) Initial OxyContin Submission Materials

All records relating to the initial approval process for OxyContin in the 1990's, including New Drug Application ("NDA") records. This includes:

- Memoranda & Reports
- Meeting Minutes
- Calendar Entries
- Approvability Correspondence
- Written or Electronic Correspondence (internal or external)
- Other Documents
- All Records relating to the drug's original label, which stated: "Delayed absorption as provided by OxyContin tablets is believed to reduce the abuse liability of the drug."

Date Range: Between Purdue Pharma's first submission for approval of the drug and the agency approval of the drug in 1995.

2) 2001 Purdue Pharma Meetings Materials

All records related to a series of meetings about OxyContin between executives from Purdue Pharma and the FDA. This includes:

- Memoranda & Reports
- Calendar Entries
- Meeting Minutes
- Written or Electronic Correspondence (internal or external)
- Other Documents

My research indicates that, at a minimum, meetings between these parties took place in April and July 2001.

Date Range: 2001.

3) OxyContin Reformulation Submission Materials

All records relating to the approval of reformulated OxyContin. This includes:

- Memoranda & Reports
- Calendar Entries
- Meeting Minutes
- Approvability Correspondence
- Other Written or Electronic Correspondence (internal or external)
- Other Documents

Date Range: From Purdue's initial application in November 2007 through the reformulated drug's approval in 2010.

4) FDA OxyContin Withdrawal Materials

All records relating to the March 2013 request by Purdue Pharma to withdraw FDA approval of the original formulation of OxyContin, for reasons of safety. This includes:

- Memoranda & Reports
- Calendar Entries
- Meeting Minutes.
- Written or Electronic Correspondence (internal or external)
- Other Documents

Date Range: 2013 & 2014.

5) FDA Correspondence Materials

All Written/Electronic Correspondence referencing OxyContin, keywords relating to OxyContin, and/or Purdue Pharma to (including cc and bcc), from, or referencing the following FDA employees:

1) David Kessler
2) Curtis Wright
3) E. Douglas Kramer
4) Diane Shnitzler
5) Sharon Hertz
6) Bob Rappaport
7) Albinus M. D'Sa
8) Janet Woodcock

6) Purdue/Sackler FDA Correspondence Materials

All Written or Electronic Correspondence to (including cc and bcc), from, or referencing:

1) Richard Sackler
2) Raymond Sackler
3) Mortimer Sackler
4) Lee Ann Storey
5) Robert Reder
6) Paul Goldenheim
7) J. David Haddox
8) Howard Udell
9) Michael Friedman

II. Search Parameters

According to FDA.gov, all records after 1938 are under FDA's jurisdiction and require permission of the agency to consult them; these are housed at the Federal Records Center in Suitland, Maryland, or at agency headquarters. Therefore I request that the agency search for all responsive records under its jurisdiction at these physical locations, in addition to searching for responsive electronic records.

III. Background and Public Interest

In 1995, the FDA approved the powerful extended-release opioid painkiller OxyContin, produced by Purdue Pharma, and, after its release in 1996, the drug became a blockbuster. Within a few years, however, there were troubling signs that OxyContin was being abused, and, even when properly used as prescribed by a physician, could lead to addiction. Over the ensuing decade, Purdue Pharma insisted that the drug was not addictive, even in the face of mounting evidence that this was not the case.

In 2007, Purdue pled guilty to federal criminal charges of misbranding OxyContin, downplaying the risk of addiction and abuse. In 2010, FDA approved a "reformulated" version of OxyContin, which was tamper-resistant and, as such, ostensibly abuse resistant. This did not stem the tide of addiction.

Hundreds of thousands of Americans have died by abusing OxyContin and other opioids, and I seek to understand the regulatory process associated with approving the drug for sale, in both its original and reformulated versions, and the interactions between Purdue Pharma and the agency.

Purdue Pharma is currently a defendant in over a thousand lawsuits, many of them brought by state and local authorities. The discovery process in these cases has already brought to light many troubling internal documents from both the FDA and Purdue Pharma relating to the approval process for the drug.

These materials will help to explain the origins of the opioid crisis and whether the FDA failed to protect Americans from a dangerous drug. It is critical for the public to learn the full story.

IV. Fee Waiver

I am an investigative journalist whose work appears in the New Yorker. In 2019, Doubleday published my non-fiction book *Say Nothing*, which investigated the period in contemporary Irish history known as "The Troubles."

Under 5 U.S.C. § 552(a)(4)(A)(iii), I am entitled to a fee waiver on the grounds that disclosure of the information sought is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government and is not primarily in the commercial interest of the requester.

V. Expedited Processing

There is a demonstrated urgency to inform the public concerning actual or alleged Federal Government activity.

As stated above, Purdue Pharma is currently a defendant in over a thousand lawsuits. There is a strong public interest in making more of this material available as quickly as possible.

VI. Certification

The above information is true and correct to the best of my knowledge.

VII. Electronic Records

Please furnish all responsive records in electronic format.

VIII. Further Correspondence

All correspondence regarding this request can be directed to me at patrick@patrickraddenkeefe.com.

Please be aware that under 5 U.S.C. § 552(a)(6)(A), a FOIA request is considered constructively denied after twenty working days.

Thank you for your prompt attention to this request.

Sincerely,

Patrick Radden Keefe